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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,112	01/14/2002	William H Cork	F-5629 (CORK 100 US)	2485

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EXAMINER

CECIL, TERRY K

ART UNIT

PAPER NUMBER

1723

DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,112

Applicant(s)

CORK ET AL.

Examiner

Mr. Terry K. Cecil

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claims 1-20, drawn to a biological suspension processing system.
- Group II, claims 21-23, drawn to a blood component storage container.
- Group III, claims 24-33, drawn to a blood processing system.
- Group IV, claims 34-45, drawn to a biological suspension processing system.

2. The inventions listed as Groups I through IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- The Special Technical Feature (STF) of Group I is a MEM sensor communicating with a fluid flow path of a treatment device.
- The STF of Group II is a blood component storage container communicating with a MEM sensor.
- The STF of Group III is an apheresis device for treating blood and having a MEM sensor in communication with a fluid flow path thereof and a data recorder.

- The STF of Group IV is a MEM sensor in communication with flow path of a blood treatment device having three flow path, wherein one flow path communicates with a human subject.

Although all of the group include the STF of a MEM sensor for sensing a biological fluid, such is known in the prior art references of Altenodorf et al. (U.S. 5,726,751); Furcht et al. (U.S. 6,054,277); and MIAN et al. (U.S. 2001/0055812 A1); therefore, that technical feature does not define a contribution over the prior art and unity is lacking among the groups.

3. During a telephone conversation with Gary McFarron on 7-8-2003 a provisional election was made with traverse to prosecute the invention of Group IV, claims 34-45. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

5. The claims are objected to because of the following informalities:

- Claim 34, line 14, "from" should be replaced with "for".
- Claim 35, "characteristic" (line 3) and "path" (line 4) should be made plural.
- Claim 40, line 1, "control" should be replaced with "controller" to maintain term consistency.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 34-36 and 38-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Mian et al. (U.S. 2001/0055812 A1), hereinafter "Mian". As shown in e.g. figure 19, Mian discloses a centrifugal blood processing system having a location (C1) where the patient places his lanced finger (see left-side-middle of figure 17F and [0216]); at this time, the flow path of C1 is in communication with the vascular system of the patient. A plurality of flow paths C2-C5 are provided for receiving the separated components (0280) to (0285), wherein the components can be withdrawn from the device (0286). The device is a microanalytic system that includes

electromechanical means (0099) and microchannels that include microsensors as disclosed by the applicant (0177) to (0208) and (0218) [as in claim 34]. Mian also teaches a controller adapted to control the treatment device in response to a signal from the sensor, e.g. pressure/flow rate sensor in the channels to control the rotation speed of the disk (0204) [as in claim 35]. Since the first flow path for inputting the blood sample communicates with the patient and the second and third flow paths communicate with the first flow path, the third flow path also communicates with the patient [as in claim 36]. The device determines the hematocrit value and the microchannel is treated with heparin to prevent clotting (0280) [as in claim 36]. As explained above, sensors are included in the flow channels to determine the flow rates therethrough (0204), the ratio of the flows (quantity) through respective channels is controlled by controlling rotational speed to optimize the separation of the blood into its components (quality) [as in claims 38-39]. The cells in the channel can also be quantified (0287). As for claims 40-45 the flow in each channel is controlled and divides the sample into its components, i.e. RBC, WBC, platelets, wherein each component can be considered as "desired" or "undesired" depending upon which component is desired to be measured.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

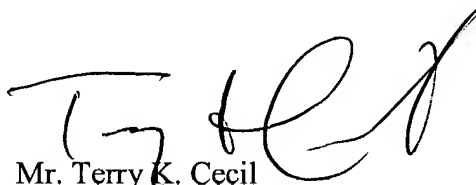
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 34-35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince (U.S. 5,178,603) in view of Bullister et al. (U.S. 6,171,253 B1), hereinafter "Bullister". Prince teaches an apheresis system for the treating/returning blood to a patient via the system shown in figure 1 including a plasma separator (treatment device) and blood pump controlling blood flow to the device and including numerous pressure sensors [as in claims 34-35]. As shown by the arrows in the figure, an inflow line to the separator is provided and two output lines [as in claim 34]. Control of the pump prevents the deleterious consequences to the patient mentioned in the abstract [as in claim 37]. Prince does not disclose a MEM sensor. Bullister teaches a MEM pressure sensor (figure 2, see col. 6, lines 4-7) for determining blood pressure [as in claim 34]. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the pressure sensor(s) of Prince to be the MEM sensor of Bullister, since Bullister teaches the benefits of precise measurement of blood pressure (col. 1, lines 39-42). Note that Bullister teaches his pressure sensor can be used in any application measuring fluid in a fluid channeling device such as pipes or catheters (col. 8, lines 15-18).

10. Contact Information:

- Examiner Mr. Terry K. Cecil can be reached at (703)305-0079 for any inquiries concerning this communication or earlier communications from the examiner.

Note that the examiner is on the increased flextime schedule but can normally be found in the office during the hours of 8:00a to 4:30p, on at least four days during the week M-F.
- The group receptionist can be reached at (703)308-0661 for inquiries of a general nature or those relating to the status of this or proceeding applications.
- Wanda Walker, the examiner's supervisor, can be reached at (703)308-0457 if attempts to reach the examiner are unsuccessful.
- Fax numbers for this art unit are as follows:
 - i. (703)872-9310 for *official* faxes (i.e. faxes to be entered as part of the file history) that are not after-final; and
 - ii. (703)872-9311 if after-final.


Mr. Terry K. Cecil
Examiner
Art Unit 1723

TKC
August 3, 2003